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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,430	REITBERG, DONALD P.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 26, 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments filed May 26, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Claims 10-14 have been withdrawn.

3. Claims 1-9 and 15-20 are examined on the merits.

IDS

4. Applicant argues that the English-translation of the AI reference was not "within the possession, custody, or control of...designated". Accordingly, Applicant submitted an English abstract of said reference (AQ). Applicant is reminded that document AQ has been considered on January 18, 2004 in the previous Office Action, mailed February 24, 2004.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-9 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. This rejection is maintained with respect to claims 1-9 and 15-20, as recited in the previous office action mailed February 24, 2004.

RESPONSE TO ARGUMENT

8. Applicant argues that "the demographic and clinical effectiveness and safety database are established in step a) and further by the step recited in dependent claim 3. Accordingly, claims 1-9 and 15-20 are not indefinite." Applicant's argument has been fully considered and found to be unpersuasive. Applicant's argument of "the demographic and clinical effectiveness and safety database are established in step a) does not resolve the vague and indefinite issue of claim 1. Claim 1 is unclear as to whether the preamble or the body of said controls the metes and bounds of said claim as discussed below. Further, claim 3 which depends from claim 1 does not resolve the vague and indefinite issue of claim 1.

9. The instant rejection identifies a plurality of limitations which cause the instant elected claims to be vague and indefinite. However, Applicant's argument is specifically directed to "the demographic and clinical effectiveness and safety database are established in step a) and further by the step recited in dependent claim 3." Due to the dependent claims embodying limitations from claim 1, it is unclear whether Applicant's argument is specific to any limitations or claims discussed below.

REJECTION RE-ITERATED

10. The preamble of claim 1 recites a method of providing demographic and clinical effectiveness and safety databases obtained from single-patient drug trials using DNA microarrays and Single Nucleotide Polymorphism (SNP), which is not consistent with the method steps of said claim. The method steps of claim 1 recite steps for conducting single-patient drug trial using by identifying genomic markers for a

individual human patient and a new individual human patient, and comparing the data directed to genomic markers for a individual human patient and a new individual human patient. Where is the demographic and clinical effectiveness and safety databases established in the instant claims? Is the simple step of comparing two data sets without specifying any criteria sufficient to determine the demographic and clinical effectiveness and safety? Clarification of the metes and bounds of the instant claim is required. Claims 2-9 and 15-20 are rejected for being dependent from claim 1.

11. Specific to claim 1, lines 10, 12, and 18, the limitation of "new individual human patient" causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a human patient is new. The limitation could reasonably be construed as a patient is new because is the individual is new to the medical practice, clinical trial, or recently acquired an illness. Clarification of the metes and bounds of the instant is required. Claims 2-9 and 15-20 are rejected for being dependent from claim 1.

12. Specific to claim 2 which depends from claim 1, the limitation of "assembling said patient population database...prior to conducting step a of said claim 1 cause the claim to be vague and indefinite because step b) assembles said database from the patient samples of step a). The instant claim is unclear as to how a patient database is assembled prior to step a) when the data necessary for the assembly of said database is generated by both steps a) and b). Clarification of the metes and bounds of the instant claim is required. Claims 3-8 are rejected for being dependent from claim 2.

13. Specific to claims 18 and 20, the claims are vague and indefinite due to said claims being respectively self-dependent.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1-9 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of providing demographic and clinical effectiveness and safety databases obtained from a single-patient drug trials using DNA microarrays and Single Nucleotide Polymorphism (SNP), does not reasonably provide enablement for said method using DNA microarrays and Single Nucleotide Polymorphism (SNP) and proteomic and successor technologies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

16. This rejection is maintained with respect to claims 1-9 and 15-20, as recited in the previous office action mailed February 24, 2004.

17. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue

experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

RESPONSE TO ARGUMENTS

18. Applicant argues that "one skilled in the art knows how to test biological materials using human DNA microarrays and Single Nucleotide Polymorphism (SNP) and proteomic and successor technologies." Applicant's argument has been fully considered and found to be unpersuasive as re-iterated below. "[I]t must be emphasized that arguments of counsel alone cannot take the place of evidence in the record once an examiner has advanced a reasonable basis for questioning the disclosure...For example, in a case where the record consisted substantially of arguments and opinions of applicant's attorney, the court indicated that factual affidavits could have provided important evidence on the issue of enablement (MPEP 2106.02).

REJECTION RE-ITERATED

19. It is acknowledged that the instant specification provides enablement disclosure for method of providing demographic and clinical effectiveness and safety databases obtained from a single-patient drug trials using DNA microarrays and Single

Nucleotide Polymorphism (SNP) (Example 9). However, the scope of the instant invention also comprises proteomic and successor technologies which causes the instant specification to not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. For example, proteomic as a field has not been exactly defined. Does the term "proteomic" used in the instant claims to refer to method directed to analyzing nucleic acid molecules, protein molecules, or others. If the term "proteomic" is directed to protein molecules which of the overwhelming number of protein analysis tools does one of skill in the art would have to select to begin using the claimed invention? Therefore, it is unclear to one of skill in the art as to what successor technologies to used to begin practice the claimed invention since these technologies have not been identified. Therefore, the lack of guidance and working for practicing the claimed invention with proteomic and successor technologies causes the instant specification to not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

CLAIM REJECTIONS - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 1-3, 6, 7, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sythowski et al. (US 6,177,244 B1) taken with FDA (1996).

23. This rejection is maintained with respect to claims 1-3, 6, 7, and 17, as recited in the previous office action mailed February 24, 2004.

RESPONSE TO ARGUMENTS

24. Applicant's argument that "rejection of claims 1-3, 6, 7, and 17 are not obvious over Sythowski in view of FDA" has been fully considered and found to be unpersuasive as re-iterated below.

REJECTION RE-ITERATED

25. Sythowski et al. discloses a method of providing a database for identifying individuals (patients) (column 37, lines 49-55) wherein said method uses the above database for monitoring effects of drugs on the expression or activity of a NPG-1 (marker) wherein the clinical monitoring process comprises determining the expression of biological markers prior and post administration of an agent (column

44, lines 1 to column 45, line 2) as directed to human prostate cancer (column 2, lines 19-26). The method of Sythowski et al. comprises using high-density arrays containing oligonucleotide probes (column 41, lines 51-56) and SNP (column 47, lines 1-16), as in claims 1-3, 6, 7, and 17.

26. However, Sythowski et al. does not specify the limitation crossover, placebo and double-blinded fashion studies.

27. The FDA via "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance" (April 1996) discloses that data from multiple clinical trials directed safety and efficacy may be applied across subgroups (crossover) to provide a clear presentation of data (page 47, §(b)). Further, the investigational product may be a pharmaceutical form of an active ingredient or placebo (page 5, §1.33) and may be conducted in a double-blinded fashion (page 3, lines 1-2), as in instant claims 1-3, 6, 7, and 17.

28. Sythowski et al. discloses a method of treatment of prostate cancer via the monitoring of clinical trial an agent directed to said cancer (column 44, lines 1 to column 45, line 2). The FDA provides guidance to one of skill in the art to safely and effectively conduct clinical trials as disclosed above.

An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the method emphasized by Sythowski et al. for a method of treatment of prostate cancer via the monitoring of clinical trial an agent directed to said cancer to utilize the guidelines of the FDA to safely and effectively conduction clinical trials. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of Sythowski et al. for

the treatment of prostate cancer via the monitoring of clinical trial an agent directed to said cancer while following the FDA guidelines.

CONCLUSION

29. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

30. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

31. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

32. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

33. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

C. Dune Ly
7/26/04

Ardin H. Marschel 8/2/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER